

VACUETTE® SECONDARY Tubes

For In Vitro Diagnostic Use
Instructions for Use

Intended Use

VACUETTE® SECONDARY Tubes are used as a secondary container for aliquoting, storing and transporting blood, blood components and urine from the primary tube in the clinical laboratory and for the analysis on laboratory analysers. The choice of tube depends on the analyser and the intended use.

Product Description

VACUETTE® SECONDARY Tubes have a dimension of 13x75 mm, are made of inert plastic (PET or PP), are non-sterile and not evacuated. They are for single use and have a maximum capacity of 5 ml. Some items are available with a SAFETY Screw Cap which includes a stopper made of bromobutyl rubber.

Tube	Temperature resistance	Instrument compatibility
SECONDARY Tube MULTIPLEX, PP 13x75mm, without cap	-80°C to +121°C	All tubes have a dimension of 13x75mm and can be used on instruments, which require a standard tube in this size as a secondary tube. Same tube design and instrument compatibility as 13x75mm VACUETTE® PREMIUM Blood Collection Tubes.
SECONDARY Tube MULTIPLEX, PET 13x75mm, without cap	-80°C to +50°C	
SECONDARY Tube MULTIPLEX, PP 13x75mm, with SAFETY Screw cap	-80°C to +50°C	
SECONDARY Tube SIMPLEX RD PET 13x75mm, without cap	-80°C to +50°C	Special tube design for Roche cobas p 612 aliquoter module.
SECONDARY Tube SIMPLEX BC, PET 13x75mm, without cap	-80°C to +50°C	Same tube design and instrument compatibility as 13x75mm VACUETTE® Blood Collection Tubes (non-ridged). Compatible with Beckman Coulter (Olympus).

Tubes can be tested and validated on the instrument directly by the user.

Precautions/Cautions

1. Do not use tubes if foreign matter is present!
2. Handle all biological samples according to the policies and procedures of your facility.
3. Biological samples may transmit HIV, HBV, HCV or other blood-borne pathogens. Obtain appropriate medical attention in the case of any exposure to biological samples and the resulting infection risk.
4. Discard all accessories in biohazard containers approved for their disposal.
5. For the correct transportation follow the guidelines of UN3373.
6. The tubes are not intended for sterilisation or autoclaving.
7. Do not re-use.
8. Snap caps for PET tubes are not intended to be used on analysers or for transport.

Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.

Storage

Exceeding the maximum or minimum recommended storage temperature may lead to impairment of the tube quality. All **VACUETTE®** SECONDARY Tubes can be stored at -80°C to +50°C prior to use.

Limitations

1. Due to possible expansion of sample material during freezing, the sample material should not exceed 3 ml.
2. Unsterile tubes are not recommended for the determination of trace elements or the use in molecular diagnostics.
3. Freezing of tubes is only recommended in open metal racks.
4. Safe transport is only ensured when the tubes are used in combination with safety caps.
5. Snap caps cannot be used in combination with SECONDARY Tube MULTIPLEX PP.
6. SAFETY Screw Caps and Snap Caps cannot be used in combination with SECONDARY Tube SIMPLEX RD.

Handling

Follow the analyser manual for the correct handling.

SIMPLEX inner cartons contain removable flaps. The perforated flaps can be opened to facilitate the pouring of tubes into some analysers.

Refer to the instrument assay's instructions for use for information on the correct sample material, the correct storage, freezing, thawing and stability.








Centrifugation

The tubes withstand a centrifugation of 4400 g for 30 minutes.

Disposal

1. The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.
2. Contaminated tubes must be disposed of in suitable biohazard disposal containers for infectious material.

Label Information

	Manufacturer		Temperature limit
	Batch code		Do not re-use
	Catalogue number		<i>In vitro</i> diagnostic medical device
	Date of manufacture		

Literature:

AUTO01-A "Laboratory Automation: Specimen Container/Specimen Carrier", Approved Standard



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Appendix - Log of changes since last revision

Location in the document	Change description
Product description	Clarification of the composition of the SAFETY Screw Cap.
Product description	Clarification of the instrument compatibility information.
Precautions/Cautions	Addition of a note regarding reporting of serious incidences in the European Union.
Limitation	Clarification that Snap Caps cannot be used with SECONDARY Tube SIMPLEX RD.
Label Information	Addition of the <i>Date of manufacture</i> symbol.